DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 13 2000

Hand Delivered

Michael D. Maves, M.D., M.B.A.
President
Consumer Healthcare Products Association
1150 Connecticut Avenue, N.W.
Washington, D.C. 20036-4193

Re: Over-the-Counter Drug Labeling (Docket No. 98N-0337/CP2)

Dear Dr. Maves:

We are writing in response to your concerns regarding the labeling of over-the-counter (OTC) drug products and your request to meet over the next several weeks to discuss several aspects of the agency's new labeling rule.

As you know, on March 17, 1999, the agency published a final rule establishing a standardized format for the labeling of all OTC drug products. 64 FR 13254 (Mar. 17, 1999); 21 CFR 201.66. The rule is intended to assist consumers in reading and understanding OTC drug labeling, in selecting among various products, and in using these products safely and effectively.

Since the early 1990's the agency has worked closely with industry, health professionals, and consumers to develop standards for the labeling of OTC drugs. Your organization has played an integral role in the process for developing these standards. As a result, the labeling rule that emerged from this process has been embraced by consumers and health professionals and, as you have emphasized to us, has generally received support from the industry.

We recognize, nevertheless, that important issues regarding the new labeling format, including the application of the rule to small package products, remain for your organization. Please be assured that we take these concerns very seriously.

On October 1, 1999, you filed a petition under 21 CFR 10.30 requesting, among other things, a two-year extension of the rule's primary implementation date. As you know, for a large majority of the products covered by the rule, compliance is not required until May 2001 (with express provision under 21 CFR 201.66(e) for deferral and with additional time for low

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volume products and products still under OTC drug monograph review). *See* 64 FR at 13274. You have asked that we further extend the primary implementation date to May 2003.

Under the agency's procedural regulations, FDA is to furnish a response to a petition filed under § 10.30 within 180 days of filing or, in this case, March, 29, 2000 (21 CFR 10.30(e)(2)). We wish to inform you that the agency has made significant progress toward answering your petition. We expect to provide our response to your petition by January 28, 2000.

Over the last several weeks you have also asked to meet with us to discuss several specific concerns regarding the new format, including the small package issues identified in your petition. On January 4, 2000, FDA's Office of Chief Counsel met with your counsel to discuss these issues and, on January 11, 2000, management from the Center for Drug Evaluation and Research and I met with you to continue the discussion.

Although you have expressed a strong interest in continuing to meet over the next several weeks, we ask that you provide us an opportunity to complete the response to your petition before requesting further discussions. Because the primary implementation date for the rule is still more than 16 months away, we believe a two-week period to allow for completion of our response is reasonable.

Thank you for your consideration.

Sincerely,

William K. Hubbard
Senior Associate Commissioner for
Policy, Planning, and Legislation

cc:

Eve E. Bachrach
Consumer Healthcare Products Association
Senior Vice President, General Counsel

Bruce N. Kuhlik (via facsimile)
Partner
Covington & Burling

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FACSIMILE TRANSMISSION RECORD

DATE: January 13, 2000

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FROM: David M. Fox
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301-827-1143 (phone)

PAGES: 3 (including cover sheet)

___ As per our discussion _X_ For your information ___ For your review and response

MESSAGE:

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